DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 8, 2015

ART Healthcare Ltd.
% Bosmat Friedman
Regulatory Affairs Consultant
MJ RAC
1208-12 Rockford Rd.
Toronto, ON M2R 3A2
Canada

Re: K142327
Trade/Device Name: smARTrack™ Feeding Tube System
smARTrack™ Feeding Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: April 30, 2015
Received: May 1, 2015

Dear Bosmat Friedman,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K142327

Device Name
smARTrack™ Feeding Tube System

Indications for Use *(Describe)*

The smARTrack™ Feeding Tube System is designed to aid qualified operators in the placement of the smARTrack Feeding Tube into the stomach of patients requiring enteral feeding. The smARTrack™ tube is equipped with sensors designed to provide information about the location of the tube tip relative to the lower esophageal sphincter (LES) thus assisting in reducing the incidence of misplacement during first positioning. The smARTrack™ tube also monitors the position continuously during the course of the feeding and automatically and in real time alerts of tube migration. The smARTrack console is equipped with a motorized mechanism which automatically and in real-time stops feeding if the feeding tube moves out of position during ongoing use. Furthermore, smARTrack™ Feeding Tube System can guide operator to correctly re-position the tube.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K142327

Device Name
smARTrack™ Feeding Tube

Indications for Use *(Describe)*
The smARTrack™ Feeding Tube is intended for gastric decompression, gastric lavage, and the administration of nutrition, fluids and medications by the naso-enteric route for patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(K) SUMMARY

[as required by section 807.92(c)]

smARTrack™ Feeding Tube System and smARTrack™ Feeding Tube

510(k) Number K142327

1. SUBMITTER

Applicant's Name:
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Date Prepared (revised):
June 5, 2015

2. DEVICE

Trade Name:
smARTrack™ Feeding Tube System
smARTrack™ Feeding Tube

Common or Usual Name:
Gastrointestinal tube and accessories

Classification:
Name: Gastrointestinal tube and accessories
Product Code: KNT
Regulation No: 876.5980
Class: 2
Classification Panel: Gastroenterology/Urology

3. PREDICATE DEVICES

Main predicate:
- CORTRAK 2 Enteral Access Device by CORPAK MedSystems; K113351

Reference devices:
- Kangaroo™ Feeding Tube with IRIS Technology by Covidien; K123555
- ZepHr Impedance/pH Reflux Monitoring System by Sandhill Scientific Inc.; K012232

4. DEVICE DESCRIPTION

The smARTrack™ Feeding Tube System is based on sensor-lined tubes that transmit real-time information to an external console. The information relayed to the console is used to transmit information about the location of the tube tip relative to the lower esophageal sphincter (LES).
The smARTrack™ System contains the following:

a) Feeding tube (multi-lumen, feeding inlet compatible with standard gravity bag unit and impedance sensors)
b) Electronic console which: indicate the location of the tube in the body, stops the feeding in case of overfeeding and keep a patient event log.

5. INDICATIONS FOR USE

smARTrack™ Feeding Tube
The smARTrack™ Feeding Tube is intended for gastric decompression, gastric lavage, and the administration of nutrition, fluids and medications by the naso-enteric route for patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

smARTrack™ Feeding Tube System
The smARTrack™ Feeding Tube System is designed to aid qualified operators in the placement of the smARTrack Feeding Tube into the stomach of patients requiring enteral feeding. The smARTrack™ tube is equipped with sensors designed to provide information about the location of the tube tip relative to the lower esophageal sphincter (LES) thus assisting in reducing the incidence of misplacement during first positioning. The smARTrack™ tube also monitors the position continuously during the course of the feeding and automatically and in real time alerts of tube migration. The smARTrack console is equipped with a motorized mechanism which automatically and in real-time stops feeding if the feeding tube moves out of position during ongoing use. Furthermore, smARTrack™ Feeding Tube System can guide operator to correctly re-position the tube.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The smARTrack™ Feeding Tube System is comprised of an electronic console which holds the system software and serves as the guiding interface to the user during initial tube placement as well as during ongoing use. The console also provides an alert when the system senses that the tube has moved out of position during ongoing use and automatically stops feeding using a motorized mechanism if such an event occurs. The feeding tube incorporates wired impedance sensors which transmit real-time information to the console regarding the feeding tube location relative to the lower esophageal sphincter.
The CORTRAK is comprised of a Monitor Unit which guides the user during initial tube placement and is also attached to a feeding tube. However, the CORTRAK utilizes an electromagnetic sensing stylet to track the path of feeding tube during a

placement procedure. The CORTRAK is dependent on the Stylet with a small coil (Transmitter) located at the tip. This Stylet is an integral part of the feeding tube inserted into a patient's stomach or small bowel but is removed after placement thus no continuous placement verification available. A Receiver Unit is placed at the Xiphoid Process to track the position of the Stylet during placement (the movement of the tube). The Receiver is attached by a cable to the Monitor Unit which then provides a graphical display of the feeding tube tip path and provides feedback to the user for proper placement.
Both systems achieve correct feeding tube placement by utilizing a different technology.
In an effort to bridge this technological gap, the smARTrack™ System has undergone bench, ex-vivo animal and clinical testing to ensure it functions correctly and achieves proper placement as well as correctly identifies tube malposition during the course of feeding. The performance data is provided in various sections of this submission. The system has successfully demonstrated its ability to guide the user in correct feeding tube placement. The system also correctly identifies tube movement and the automatic mechanism which stops the feeding has also been validated.
In the clinical study which was conducted, tube placement was initially verified with the System and a confirmatory X-Ray ("gold standard" placement verification) was performed. In all cases the System successfully guided the user to ensure correct placement was achieved.
The available performance data supports the safety and effectiveness profile of the system and negates the technological differences between the smARTrack and its predicate devices.

The CORTRAK feeding tubes are available in 8, 10 and 12 Fr. The smARTrack feeding tube is available in 14Fr only. There are many FDA cleared feeding tubes which are available in various sizes ranging from 6 to 21 Fr. Therefore, this difference in tube diameter does not raise any new safety or effectiveness concerns as both devices are intended to be used in adult patients. Furthermore, biocompatibility tests were also performed to ensure the tubes are safe for use.

The operational principle of the impedance sensors incorporated in the feeding tube is similar to that of FDA cleared Sandhill scientific zephyr impedance probe device. Both the smARTrack feeding Tube and the Sandhill are designed to be used in the upper GI tract; therefore, no new safety and effectiveness concerns are raised as a result of incorporating the impedance sensors in the feeding tube.

7. PERFORMANCE DATA

Below is a list of the tests that have been performed and successfully completed for the smARTrack™ Feeding Tube System.

Biocompatibility:
The biocompatibility evaluation for the smARTrack System feeding tube was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within

a Risk Management Process," as recognized by FDA. The feeding tube component is considered a surface contacting devices with prolonged mucosal membrane contact. The battery of testing included the following tests:

- Cytotoxicity Study Using the ISO Elution Method
- Systemic Injection Test
- ISO Intracutaneous Study in Rabbits
- Implantation and Subacute Toxicity Study in the Rabbit

Electrical safety and electromagnetic compatibility (EMC):
The system was tested and found to comply with IEC 60601-1:2005/EN 60601-1:2006 Medical electrical equipment -Part 1: General requirements for basic safety and essential performance3rd Ed and IEC 60601-1-2:2007 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests.

Software Verification and Validation Testing:
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could result in minor injury to the patient.

Bench:

- Minimal bending possible to the tube
- smARTrack feeding tube in HCL
- Evaluation of the tensile properties
- Liquid leakage test
- Lumen flow rate measurements
- Resistance to leakage during aspiration or vacuum
- Misconnection testing
- Motorized mechanism performance during displacement

Animal:

- Ex-Vivo Testing:
  The study was conducted to evaluate the performance of the Interactive Nasogastric Tubes (INGT) and System (i.e., smART/smARTrack System). The study was conducted utilizing adult pig's stomach, trachea and esophagus without hernia. Proper functionality of the sensors was confirmed.
- In-Vivo Testing:
  The study was conducted to evaluate the following: safe operation of the feeding tube without damaging the esophagus or the stomach, effectiveness of the feeding using the impedance sensors, right position of the feeding tube in the LES by using the location sensors, ability of controlling and stopping the feeding operation.
  The study was conducted on an adult pig (60kg) under anesthesia.

The study confirmed that the Feeding Tube position sensors work very well and identify the correct location of the LES.

Clinical:

A feasibility study was conducted on 10 healthy volunteers to assess the functionality and safety of the system. No unexpected Adverse Events were reported. Tube insertions in all subjects were successful with no major issues reported. The entire procedure was pretty well tolerated by the subjects. Most patients that undergo feeding tube insertion experience some pain and discomfort and therefore none of the feedback that was received from the healthy volunteers was unexpected. It should be noted that the main target population for the system would be unconscious or anesthetized patients for whom minor pain and discomfort would be negligible. Furthermore, according to the patients subjective feedback, throughout the procedure, no severs pain or discomfort was recorded.

The convenience of the feeding tube insertion was assessed via questionnaires completed by the clinical staff. Correct placement of the tube was verified via X-Ray. No incorrect placements occurred while using the feeding tube.

Conclusion:

The smARTrack™ Feeding Tube System has similar intended use as CORTRAK and similar indications for use as the CORTRAK and Kangaroo predicate devices. Furthermore, the smARTrack™ is substantially equivalent in technological and performance characteristics to the CORTRAK predicate as well as to the two reference devices (Kangaroo™ and ZepHr).

Consequently, it is clear that the smARTrack™ Feeding Tube System is as safe and effective as its predicate devices without raising any new safety and/or effectiveness concerns. Any differences have been addressed by extensive testing and validations and therefore negate any safety or effectiveness concerns.